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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/066,305 | 01/31/2002 | Todd R. Golub | 2825.2023-001 | 2026 |

21005 7590 10/15/2002

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[REDACTED] EXAMINER

CANELLA, KAREN A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 10/15/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|-----------------------------|
| Office Action Summary | Application No. 10/066,305 | Applicant(s) Golub et al |
| | Examiner Karen Canella | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

DETAILED ACTION

1. Claims 12, 13, 24, 25 and 28-30 have been amended.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 12-20, 23-33, drawn to a an oligonucleotide micro array, a method of classifying a brain tumor, a method of predicting the efficacy or treating a brain tumor, a method of assigning a brain tumor sample to a treatment class, a method for evaluating drug candidates for their effectiveness in treating brain tumors, and a method for predicting tumorigenesis, all methods comprising the determination of a gene expression profile by means of detecting polynucleotides, classified in class 435, subclass 6. Claims 1-6, 12-17, 23-29 and 31-33 will be examined with this group to the extent that the claims read on the detection of polynucleotides.
 - II. Claims 1-6, 10-17, 21-29 and 31-33, drawn to a method of classifying a brain tumor, a method of predicting the efficacy or treating a brain tumor, a method of assigning a brain tumor sample to a treatment class, a method for evaluating drug candidates for their effectiveness in treating brain tumors, and a method for predicting tumorigenesis, all methods comprising the determination of a gene expression profile by means of detecting polypeptides, classified in, for example, class 435, subclass 7.1. Claims 1-6, 12-17, 23-29 and 31-33 will be examined with this group to the extent that the claims read on the detection of polypeptides.
3. The inventions are distinct, each from the other because of the following reasons:
The methods of Groups I and II differ in the method objectives, method steps and parameters and in the reagents used.

Art Unit: 1642

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

4. With the election of either Invention, a further election of a single gene from those listed in Tables 1 through 6, or *Zic* or *NSCL-1* or *TrkC* is required. Each gene is structurally and functionally a different product. The examination of all genes would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues. Because these genes are distinct for the reasons given above and because the searches required for the genes are not co-extensive, restriction for examination purposes is considered proper.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

Art Unit: 1642

be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella
Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

October 12, 2002